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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,279	07/18/2001	Kazumi Iijima	K0208-013	5027
38492	7590	04/09/2004	EXAMINER	
WILKIE FARR & GALLAGHER LLP INTELLECTUAL PROPERTY LEGAL ASSISTANTS 787 SEVENTH AVE NEW YORK, NY 10019-6099			AUGHENBAUGH, WALTER	
			ART UNIT	PAPER NUMBER
			1772	
DATE MAILED: 04/09/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,279

Applicant(s)

IIJIMA, KAZUMI

Examiner

Walter B Aughenbaugh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 17, 2003 has been entered.

Acknowledgement of Applicant's Amendments

2. The amendments made in claims 1, 3 and 5 in the Amendment filed November 17, 2003 (Amdt. B) have been received and considered by Examiner.
3. The cancellation of claims 2 and 4 in Amdt. B has been acknowledged by Examiner.
4. The status of claim 6 that is drawn to a nonelected group, i.e. the status of claim 6 as considered by Applicant, is not clear after a review of the record. Please clarify in the next reply.
5. The set of claims submitted in Amdt. B does not comply with the Revised Amendment Practice effective July 30, 2003 (37 CFR 1.121). The next set of claims to be submitted must comply with the Revised Amendment Practice. N.B. all claims that have been presented during prosecution must be listed in order and must be labeled with the appropriate status identifier, e.g. "2. (canceled)". Claim 6 must also be included: "6. (canceled)" or "6. (withdrawn)".

WITHDRAWN REJECTIONS

6. The 35 U.S.C. 112 rejection of claim 1 repeated in paragraph 8 of Paper 9 has been withdrawn due to Applicant's amendments to claim 1 in Amdt. B.

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7. The 35 U.S.C. 102 rejection of claim 1 made of record in paragraph 9 of Paper 9 has been withdrawn due to Applicant's amendments to claim 1 in Amdt. B.

8. The 35 U.S.C. 103 rejections of claims 3 and 5 made of record in paragraphs 10 and 12 of Paper 9 have been withdrawn due to Applicant's amendments to claims 1 and 5 in Amdt. B.

9. The 35 U.S.C. 103 rejections of claims 2 and 4 made of record in paragraphs 10 and 11 of Paper 9 have been withdrawn due to Applicant's cancellation of claims 2 and 4 in Amdt. B.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

10. Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regard to claim 1, the recitation "using cyclic polyolefin resin as a material" renders the claim indefinite: "as a material" for or of what? Claim 1 provides for the use of cyclic polyolefin, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

In further regard to claim 1, "a nozzle portion" of what?

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In regard to claim 3, insertion of --of a-- between “or” and “screw” in the third line of the claim would make the claim read more clearly.

Claim Rejections - 35 USC § 102

11. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Moncada et al.

Moncada et al. teach a syringe barrel (the combination of syringe barrel, item 84 and adapter, item 80, having a generally continuous surface at the junction of the syringe and the barrel and the adapter, see Fig. 5) comprising a luer lock portion (the combination of items 108 and 116 and the space between items 108 and 116, Fig. 5) formed in a nozzle portion (adapter body, item 20, Fig. 1 and 2 and adapter, item 80, Fig. 5) and comprising an inner cylinder (cylindrical portion, item 30, Fig. 1 and male Luer lock connector portion, item 106, Fig. 5) and an outer cylinder (flanges, item 116, Fig. 5 and corresponding unlabelled flanges in Fig. 1) (col. 3, lines 62-67, col. 4, lines 2-4, col. 5, line 48-col. 6, line 20). Moncada et al. teach that the inner cylinder (cylindrical portion, item 30, Fig. 1) has ears (item 34, Fig. 1) for securing a Luer lock portion (item 24, Fig. 1) that is continuous with the inner cylinder (item 30) into a cooperating Luer lock portion (col. 4, lines 4-6). Moncada et al. teach that the outside surfaces of the ears (item 34) include teeth (item 48) and that teeth or any other type of roughened surface are formed on the rear surface (item 50, Fig. 1) of the ears (item 34) (col. 4, lines 42-60 and Fig. 1 and 2). The ears, item 34 of Fig. 1, correspond to the ears, item 112 of Fig. 5 (col. 5, line 64-col. 6, line 6); therefore, Moncada et al. teach that part of an outer peripheral surface of the inner cylinder has a roughened surface. The syringe barrel of Moncada et al. is necessarily filled with air; the recitation “pre-filled” is a method limitation that has not been given patentable weight

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since the method of forming the syringe barrel is not germane to the issue of patentability of the syringe barrel itself: in regard to examination of article claims, the Office is concerned only with the structure and composition, where applicable, of the final product; therefore, the prefix “pre-” in “pre-filled” has not been given patentable weight. The recitation “using cyclic polyolefin resin as a material” does not positively recite anything about any component of the syringe barrel as claimed.

In regard to claim 5, the recitation “wherein said roughened surface is a surface formed by blast treatment” is a method limitation that has not been given patentable weight since the method of forming the syringe barrel is not germane to the issue of patentability of the syringe barrel itself.

Claim Rejections - 35 USC § 103

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moncada et al.

Moncada et al. teach the syringe barrel as discussed above. Moncada et al. teach a Luer lock connector having ears (item 122) on the male Luer lock portion of the needle mount (item 94) and threads (item 124) on the female Luer lock portion (item 118) (col. 6, lines 7-16 and Fig. 5). Moncada et al. teach that the threaded engaging means or other engaging means may be positioned at any other location along the length of the adapter (item 80) (col. 6, lines 19-23). The portion of the female Luer lock portion (item 118) that has threads (item 124) corresponds the outer cylinder as claimed; Moncada et al. therefore teach that the inner peripheral surface of the outer cylinder contains a helically continuous screw thread.

Moncada et al. fail to explicitly teach that the surface of the screw thread or screw root portion formed between adjacent ridges of the screw thread specifically has a roughened surface.

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However, since Moncada et al. teach that the outside surfaces and rear surface (item 50) of the ears (item 34) have teeth or any other type of roughened surface for increased frictional engagement between the ears and a cooperating female Luer lock portion (col. 4, lines 42-53) and that the threaded engaging means or other engaging means may be positioned at any other location along the length of the adapter (item 80) (col. 6, lines 19-23), one of ordinary skill in the art would have recognized to have formed threads (item 124) on the inner peripheral surface of outer cylinder (item 116) when required depending on the desired end use of the product as taught by Moncada et al. and to have formed teeth or any other type of roughened surface on the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed teeth or any other type of roughened surface on the threads (item 124) of Moncada et al. in order to increase frictional engagement between the threads and the cooperating portion when required depending on the desired end use of the product as taught by Moncada et al.

ANSWERS TO APPLICANTS ARGUMENTS

13. Applicant's arguments regarding the 35 U.S.C. 102 rejection of claim 1 as anticipated by Moncada et al. made of record in paragraph 9 of Paper 9 have been fully considered but are not persuasive. In response to Applicant's argument on the top of page 4 of Paper 11 that "adapter 80 therefore does not extend from the nozzle portion of the syringe barrel", the limitations on which the Applicant relies (i.e. the adapter extending from the nozzle portion) are not stated in the

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claims. It is the claims that define the claimed invention, and it is the claims, not specifications that are anticipated or unpatentable. *Constant v. Advanced Micro-Devices Inc.*, 7 USPQ2d 1064. Applicant also argues that the luer lock connector taught by Moncada et al. is not “formed in the nozzle portion” but this limitation was newly added to claim 1 in Paper 11 and has not been entered for the reasons discussed above in paragraph 1 of this Advisory Action.

Applicant then argues that Moncada et al. doesn't teach that all or part of an inner surface of the luer lock portion has a roughened surface; Applicant seems to have neglected the sentence prior to the sentence including the statement that “all or part of an inner surface of the luer lock portion (the combination of items 108 and 116 and the space between items 108 and 116, Fig. 5) has a roughened surface” that explains the reason why Moncada et al. teach that all or part of an inner surface of the luer lock portion has a roughened surface: “Moncada et al. teach that the outside surfaces of the ears (item 34) include teeth (item 48) and that teeth or any other type of roughened surface are formed on the rear surface (item 50, Fig. 1) of the ears (item 34) (col. 4, lines 42-60 and Fig. 1 and 2)”. Since the outside surfaces of the ears are part of the inner surface of the luer lock portion, Moncada et al. teach that all or part of an inner surface of the luer lock portion has a roughened surface.

14. Applicant's arguments regarding the 35 U.S.C. 103 rejection of claim 4 over Moncada et al. in view of Porfano et al. made of record in paragraph 11 of Paper 9 have been fully considered but are not persuasive. Applicant argues that “the technical field and purpose of Porfano et al. differ from that of the claimed invention on pages 4-5 of Paper 11. As Applicant acknowledges on page 5 of Paper 11, and as is made of record in paragraph 11 of Paper 9, the Porfano et al. deals with plastic syringe barrels (it is stated in paragraph 11 of Paper 9 that

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“Porfano et al. teach that cyclic polyolefin copolymers are suitable plastics to use as the syringe barrel material since cyclic polyolefin copolymers typically do not require a clarifying agent (col. 6, lines 46-48)”). One of ordinary skill in the art would have consulted the Porfano et al. reference that teaches a suitable material for plastic syringe barrels in order to determine the type of material to use for the plastic syringe barrel of Moncada et al.

15. Applicant’s arguments regarding the 35 U.S.C. 103 rejection of claim 3 over Moncada et al. made of record in paragraph 10 of Paper 9 have been fully considered but are not persuasive. Applicant argues that Moncada et al. does not teach that “any frictional engaging means (including teeth or a roughened surface, col. 4, lines 45-50) may be positioned at any other location along the length of the adapter (col. 6, lines 19-23)” as the Office Action (Paper 9) states in paragraph 10. The cited passage in col. 6 states that “the threaded engaging means or other engaging means may be positioned at any other location along the length of the adapter”, and the cited passage from col. 4 plainly states that the teeth are “for increased frictional engagement between the ears 34 and a cooperating female Luer lock portion”; Moncada et al. clearly consider the teeth to be an engaging means- not the threaded engaging means, but an engaging means that falls within the “other engaging means” genus that is taught at col. 6, line 21 of Moncada et al.

16. Applicant’s arguments regarding the 35 U.S.C. 103 rejection of claim 5 over Moncada et al. in view of Lampkin made of record in paragraph 12 of Paper 9 have been fully considered but are not persuasive. Applicant argues that the purpose of the roughened area Lampkin is “entirely different” than the purpose of the claimed invention, but the purpose of the roughened area of Lampkin is irrelevant; Lampkin teaches a method by which a roughened area is formed. One of

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ordinary skill in the art would have consulted Lampkin for a method of forming a roughened surface on a plastic syringe since Lampkin teaches a syringe having a roughened surface.

Conclusion

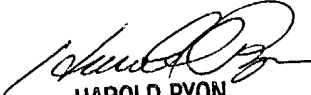
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh
04/01/04

WBA


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

4/1/04